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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,337	03/29/2004	Bill J. Peck	10040506-1	5083

22878 7590 05/11/2007

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,337	PECK ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,27 and 28* is/are pending in the application.

4a) Of the above claim(s) *17-24,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 27 February 2007 in which claims 1, 10-11were amended, claim 25 was canceled and claim 28 was added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 5 December 2006 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) are withdrawn in view of the amendments. The previous rejections under obviousness-type double patenting are maintained because the Terminal Disclaimers do not comply with the requirements. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-16 and 28 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 5,186,824, issued 16 February 1993) in view of Schleifer (A) (U.S. Patent No. 6,077,674, issued 20 June 2000) or Schleifer (B) (U.S. Patent No. 6,309,828, issued 30 October 2001).

Regarding Claim 1, Anderson et al disclose a method of producing an array of at least two different polymeric ligands (e.g. oligonucleotides synthesized on a solid support (e.g. particle, membrane, disc Column 6, lines 49-56) the two different sequences being e.g. product and failed sequences, Column 20, lines 10-25).

Anderson et al disclose the method comprising contacting a blocked monomer at first and second locations having functional groups (e.g. cpg supports having the first monomer attached, Column 19, lines 55-58) under conditions sufficient for the monomer to covalently bond to the surface, removing blocking groups to generate a function group and reiterating the steps to produce the array of at least two ligands (Column 19, line 55-Column 20, line 50). Anderson et al further the method wherein the solid supports are exposed to reagents sequentially wherein the reagents are kept separate based on density (Column 5, lines 3-38 and Column 6, lines 13-36) forming a liquid-liquid interface such that the solid support is not exposed to a triple phase interface (Column 12, lines 28-67 and Fig. 2A-2D).

While the reference does not use the term "array", the term is defined by dictionary.reference.com as "a larger group, number or quantity of people or things". Anderson et al teach production of a plurality of oligonucleotides attached to cpg substrate ("1. Oligonucleotide Synthesis", Columns 19-22 and Column 24, lines 5-35).

Anderson et al further teaches the method wherein the polymers are cleaved from the support for subsequent use and/or immobilization (Column 14 and Column 20, liens 10-25) e.g. hybridization to oligonucleotides immobilized on solid supports (Column 20, lines 20-21). The clearly suggests that the polymers are subsequently immobilized, but Anderson et al does not specifically teach production of an addressable array.

However, polymer synthesis on cpg supports followed by polymer cleavage for production of an addressable array was well known and routinely practiced in the art at the time the claimed invention was made as taught by Schleifer (A) and (B).

Schleifer (A) teaches a similar method of polymer synthesis comprising repeated monomer additions to cpg supports (Column 9, lines 6-10), cleavage of the polymers from the supports (Column 10, lines 10-15) and immobilization of the polymers to feature locations on the array (Column 10, lines 37-42) whereby "costly and time consuming purification step" is avoided while providing a high purity full-length oligonucleotide array (Column 10, lines 47-51).

Schleifer (B) also teaches a similar method of polymer synthesis comprising repeated monomer additions to cpg supports, cleavage of the polymers from the supports and immobilization of the polymers to feature locations on the array (Column 9, lines 22-Column 10, line 30 and Example 3) whereby an addressable array is produced (see definition of array, Column 1, lines 13-15). Schleifer (B) teaches this polymer synthesis coupled to array production is an efficient, cost-effective method of spatially integrating polymer synthesis and replicate array fabrication (Abstract, Column 2, lines 22-31).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polymers synthesized by Anderson et al to the further step of addressable array fabrication taught by Schleifer (A) and/or (B). One of ordinary skill in the art would have been motivated to do so based on the well known practice of addressable immobilization of pre-synthesized polymers as taught by Schleifer (A) and (B). One of ordinary skill would have been further motivated to do so for the expected benefits of producing replicate arrays via efficient, cost-effective methods of spatially integrating polymer synthesis and array fabrication (Schleifer (B):Abstract, Column 2, lines 22-31) and for the further benefits of providing high purity full-length oligonucleotides while avoiding "costly and time consuming purification step" (Schleifer (A): Column 10, lines 47-51).

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the displacement fluid synthesis steps of Anderson et al to the polymer synthesis of either Schleifer (A) or (B). Anderson et al teaches polymer

synthesis in particulate beds is problematic in that fluid flow thorough the bed is non-uniform resulting non-uniform reactions and hence inefficient and inaccurate polymer synthesis (Columns 1-4). Anderson et al further teach that their method of precise fluid control through the particle bed minimizes the problems of micro and macro-anomalous flow provides precise and efficient polymer synthesis (Column 5-6). Therefore, one of ordinary skill in the art would have been motivated to apply the precisely controlled fluid flow of Anderson et al to the particle bed synthesis of Schleifer (A) and/or (B) for the expected benefit of precise and efficient polymer synthesis while eliminating the problems inherent in particle bed synthesis as taught by Anderson (Columns 1-6).

Regarding Claim 2, Anderson et al disclose the method wherein the functional group generation comprises sequentially contacting at least a portion of the surface with a plurality of liquids (Column 6, line 57-Column 7, line 14).

Regarding Claim 3, Anderson et al disclose the method wherein the different liquids include at least an oxidizing liquid and a deblocking liquid (Column 13, line 59-Column 14, line 11 and Column 19, line 55-Column 20, line 50).

Regarding Claim 4, Anderson et al disclose the method wherein the liquids further include a wash liquid (Column 13, line 59-Column 14, line 11 and Column 19, line 55-Column 20, line 50).

Regarding Claim 5, Anderson et al disclose the method wherein the different liquids further include a capping liquid (Column 13, line 59-Column 14, line 11 and Column 19, line 55-Column 20, line 50).

Regarding Claim 6, Anderson et al disclose the method wherein the sequentially applied liquids have a different density (Column 6, line 57-Column 7, line 14).

Regarding Claim 7, Anderson et al disclose the method wherein the sequentially applied liquids have a different density greater than zero (i.e. increasing density, Column 6, line 57-Column 7, line 14).

Regarding Claim 8, Anderson et al disclose the method wherein the sequential contact is by displacing a previous liquid with an immediately subsequent liquid (Column 7, line 60-Column 8, line 3 and Column 12, lines 28-67 and Fig. 2A-2D).

Regarding Claim 9, Anderson et al disclose the method wherein displacing comprises flowing the subsequent liquid across the surface to produce a stratified liquid interface that moves across the surface (Column 12, lines 28-67 and Fig. 2A-2D).

Regarding Claim 10-11, Anderson et al disclose a method of producing an array of at least two different polymeric ligands (e.g. oligonucleotides synthesized on control pore glass, the two different sequences being e.g. product and failed sequences, Column 20, lines 10-25).

Anderson et al disclose the method comprising contacting a blocked monomer at first and second locations having functional groups (e.g. cpg supports having the first monomer attached, Column 19, lines 55-58) under conditions sufficient for the monomer to covalently bond to the surface, removing blocking groups to generate a function group and reiterating the steps to produce the array of at least two ligands (Column 19, line 55-Column 20, line 50). Anderson et al teach the method wherein the solid supports are exposed to reagents sequentially wherein the reagents are kept separate based on density (Column 5, lines 3-38 and Column 6, lines 13-36) forming a liquid-liquid interface such that the solid support is not exposed to a triple phase interface (Column 12, lines 28-67 and Fig. 2A-2D).

Anderson et al further teach the method wherein the flow rate is controlled and monitored during passage of reagents (Column 5,lines 25-27; Column 14, lines 44-53 21) and further teach that it is important to control the flow rate because some synthesis steps take more or less time than other steps and because reagent waste resulting from excess use of reagents is expensive (Column 21, lines 30-65) but they are silent regarding specific flow rates. However, the reference clearly suggests that the flow rate is adjusted to maximize reagents and synthetic step. Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the flow rate during the synthesis steps of

Anderson to obtain optimal flow rates (e.g. about 1-20 cm/x). One of ordinary skill in the art would have been motivated to do adjust the flow rate so as to maximize syntheses reaction with minimal waste of reagents as desired by Anderson et al (Column 21, lines 30-65).

Regarding Claim 12, Anderson et al disclose the method wherein step (b) is preformed in a flow cell i.e. internal space for fluid flow so as to contact solid support (Column 5, lines 20-38).

Regarding Claim 13, Anderson et al disclose the method comprising contacting a blocked monomer at first and second locations having functional groups (e.g. supports having the first monomer attached, Column 19, lines 55-58) under conditions sufficient for the monomer to covalently bond to the surface, removing blocking groups to generate a function group and reiterating the steps to produce the array of at least two ligands (Column 19, line 55-Column 20, line 50). Anderson et al do not teach monomers addition using a pulse-jet.

However, Schleifer et al teaches the similar method of polymer synthesis utilizing pulse-jet addition of monomers during multi-step synthesis of polymers (Column 10, lines 27-31).

Regarding Claim 14, Anderson et al disclose the method wherein functional group generation comprising contacting the surface in a flow cell with a plurality of different liquids in the following order: oxidizing, wash, daglock, wash wherein the liquids are contacted sequentially by displacing the previous liquid (Column 7, line 60-Column 8, line 3 and Column 12, lines 28-67 and Fig. 2A-2D and (Column 19, line 55-Column 20, line 50).

Regarding Claim 15, Anderson et al disclose the method wherein the sequential contact is by displacing a previous liquid with an immediately subsequent liquid (Column 7, line 60-Column 8, line 3 and Column 12, lines 28-67 and Fig. 2A-2D).

Regarding Claim 16, Anderson et al disclose the method further comprising contacting a capping liquid which is contacted with the surface between an oxidizing liquid and deblocking liquid (Column 19, line 55-Column 20, line 50).

Regarding Claim 28, Anderson et al disclose the method wherein the substrate is a planar substrate e.g. "flat discs", Column 6, lines 49-52).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-16 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-59 of copending Application No. 10/813,467. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate and differ only that the instant claims are drawn to the generic polymers i.e. ligands and monomers while the'467 claims are drawn to a species i.e. oligonucleotide and nucleotides. However, the courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed ligands (i.e. genus) are obvious in view of the '467 oligonucleotide. The claim sets further differ in that the instant claims are drawn to displacing fluid without a triple phase interphase, while the' 467 defines the same step as "displacing with a purging fluid".

However, dependent claims (e.g. claim 8) define the instantly claimed lack of triple phase interphase as being via a displacing fluid. Therefore, the claim sets are drawn to very similar methods that are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-16 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 11/234,701. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate and differ only that the instant claims are drawn to the generic polymers i.e. ligands and monomers while the'701 claims are drawn to a species i.e. nucleic acid molecule and nucleosides. However, the courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed ligands (i.e. genus) are obvious in view of the '701 nucleic acid molecule. The claim sets further differ in that the instant claims are drawn to displacing fluid without a triple phase interphase, while the' 701 defines the same step as displacing. However, dependent claims (e.g. claim 8) define the instantly claimed lack of triple phase interphase as being via a displacing. Therefore, the claim sets are drawn to very similar methods that are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-16 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending

Application No. 10/813,331. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate and differ only that the instant claims are drawn to the generic polymers i.e. ligands and monomers while the'331 claims are drawn to a species i.e. nucleic acid and nucleosides. However, the courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed ligands (i.e. genus) are obvious in view of the '331 nucleic acid. The claim sets further differ in that the instant claims are drawn to displacing fluid without a triple phase interphase, while the' 331 defines the same step as displacing. However, dependent claims (e.g. claim 8) define the instantly claimed lack of triple phase interphase as being via displacing. Therefore, the claim sets are drawn to very similar methods that are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-16 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 11/082,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for producing polymers on a substrate and differ only that the instant claims are drawn to the generic polymers i.e. ligands and monomers while the'006 claims are drawn to a species i.e. nucleic acids and peptides (Claims 12-18). However, the courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed ligands (i.e. genus) are obvious in view of the '467 oligonucleotide. The

claim sets further differ in that the instant independent claims are drawn to displacing fluid without a triple phase interphase e.g. spatially controlled displacing, while dependent claim 9 of the '006 method defines the fluid movement as spatially controlled. Therefore, the claim sets are drawn to very similar methods that are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response

9. Applicant states that Terminal Disclaimers have been submitted to overcome the above rejections under obviousness-type double patenting. The Terminal Disclaimers are not sufficient to overcome the rejections because 1) each disclaimer must be signed by an attorney and 2) the attorney signing the disclaimers must be of record.

The rejections are maintained and made final.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

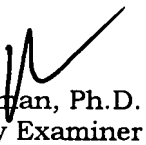
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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Primary Examiner
Art Unit: 1634
May 10, 2007